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October 15, 1992

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Attn: Section 8(e) Coordinator (CAP Agreement)

Dear Coordinator:

8ECAP-0025

On behalf of the Regulatee and pursuant to Unit II B.1.b. and Unit II C of the 6/28/91 CAP Agreement, E.I. Du Pont de Nemours and Co. hereby submits (in triplicate) the attached studies. Submission of this information is voluntary and is occasioned by unilateral changes in EPA's standard as to what EPA now considers as reportable information. Regulatee's submission of information is made solely in response to the new EPA §8(e) reporting standards and is not an admission: (1) of TSCA violation or liability; (2) that Regulatee's activities with the study compounds reasonably support a conclusion of substantial health or environmental risk or (3) that the studies themselves reasonably support a conclusion of substantial health or environmental risk.

The "Reporting Guide" creates new TSCA 8(e) reporting criteria which were not previously announced by EPA in its 1978 Statement of Interpretation and Enforcement Policy, 43 Fed Reg 11110 (March 16, 1978). The "Reporting Guide states criteria which expands upon and conflicts with the 1978 Statement of Interpretation. Absent amendment of the Statement of Interpretation, the informal issuance of the "Reporting Guide" raises significant due processes issues and clouds the appropriate reporting standard by which regulated persons can assure TSCA Section 8(e) compliance.

Mark H. Christman

Counsel

Legal D-7158

1007 Market Street

Wilmington, DE 19898

(302) 774-6443



ATTACHMENT 1

Submission of information is made under the 6/28/91 CAP Agreement, Unit II. This submission is made voluntarily and is occasioned by recent changes in EPA's TSCA §8(e) reporting standard; such changes made, for the first time in 1991 and 1992 without prior notice and in violation of Regulatee's constitutional due process rights. Regulatee's submission of information under this changed standard is not a waiver of its due process rights; an admission of TSCA violation or liability, or an admission that Regulatee's activities with the study compounds reasonably support a conclusion of substantial risk to health or to the environment. Regulatee has historically relied in good faith upon the 1978 Statement of Interpretation and Enforcement Policy criteria for determining whether study information is reportable under TSCA §8(e), 43 Fed Reg 11110 (March 16, 1978). EPA has not, to date, amended this Statement of Interpretation.

After CAP registration, EPA provided the Regulatee the June 1, 1991 "TSCA Section 8(e) Reporting Guide". This "Guide" has been further amended by EPA, EPA letter, April 10, 1992. EPA has not indicated that the "Reporting Guide" or the April 1992 amendment supersedes the 1978 Statement of Interpretation. The "Reporting Guide" and April 1992 amendment substantively lowers the Statement of Interpretation 's TSCA §8(e) reporting standard². This is particularly troublesome as the "Reporting Guide" states criteria, applied retroactively, which expands upon and conflicts with the Statement of Interpretation.³ Absent amendment of the Statement of Interpretation, the informal issuance of the "Reporting Guide" and the April 1992 amendment clouds the appropriate standard by which regulated persons must assess information for purposes of TSCA §8(e).

²In sharp contrast to the Agency's 1977 and 1978 actions to soliciting public comment on the proposed and final §8(e) Policy, EPA has unilaterally pronounced §8(e) substantive reporting criteria in the 1991 Section 8(e) Guide without public notice and comment, See 42 Fed Reg 45362 (9/9/77), "Notification of Substantial Risk under Section 8(e): Proposed Guidance".

³A comparison of the 1978 <u>Statement of Interpretation</u> and the 1992 "Reporting Guide" is a appended.

Throughout the CAP, EPA has mischaracterized the 1991 guidance as reflecting "longstanding" EPA policy concerning the standards by which toxicity information should be reviewed for purposes of §8(e) compliance. Regulatee recognizes that experience with the 1978 Statement of Interpretation may cause a review of its criteri. Regulatee supports and has no objection to the Agency's amending reporting criteria provided that such amendment is not applied to the regulated community in an unfair way. However, with the unilateral announcement of the CAP under the auspices of an OCM enforcement proceeding, EPA has wrought a terrific unfairness since much of the criteria EPA has espoused in the June 1991 Reporting Guide and in the Agency's April 2, 1992 amendment is new criteria which does not exist in the 1978 Statement of Interpretation and Enforcement Policy.

The following examples of new criteria contained in the "Reporting Guide" that is not contained in the <u>Statement of Interpretation</u> follow:

- o even though EPA expressly disclaims each "status report" as being preliminary evaluations that should <u>not</u> be regarded as final EPA policy or intent⁴, the "Reporting Guide" gives the "status reports" great weight as "sound and adequate basis" from which to determine mandatory reporting obligations. ("Guide" at page 20).
- o the "Reporting Guide" contains a matrix that establishes new numerical reporting "cutoff" concentrations for acute lethality information ("Guide" at p. 31). Neither this matrix nor the cutoff values therein are contained in the <u>Statement of Interpretation</u>. The regulated community was not made aware of these cutoff values prior to issuance of the "Reporting Guide" in June, 1991.
- othe "Reporting Guide" states new specific definitional criteria with which the Agency, for the first time, defines as 'distinguishable neurotoxicological effects'; such criteria/guidance not expressed in the 1978 Statement of Interpretation.⁵;

othe "Reporting Guide" provides new review/ reporting criteria for irritation and sensitization studies; such criteria not previously found in the 1978 <u>Statement of Interpretation/Enforcement Policy</u>.

othe "Reporting Guide" publicizes certain EPA Q/A criteria issued to the Monsanto Co. in 1989 which are not in the <u>Statement of Interpretation</u>; have never been published in the <u>Federal Register</u> or distributed by the EPA to the Regulatee. Such Q/A establishes new reporting criteria not previously found in the 1978 <u>Statement of Interpretation/Enforcement Policy</u>.

⁴The 'status reports' address the significance, if any, of particular information reported to the Agency, rather than stating EPA's interpretation of §8(e) reporting criteria. In the infrequent instances in which the status reports contain discussion of reportability, the analysis is invariably quite limited, without substantial supporting scientific or legal rationale.

⁵ See, e.g., 10/2/91 letter from Du Pont to EPA regarding the definition of 'serious and prolonged effects' as this term may relate to transient anesthetic effects observed at lethal levels; 10/1/91 letter from the American Petroleum Institute to EPA regarding clarification of the Reporting Guide criteria.

In discharging its responsibilities, an administrative agency must give the regulated community fair and adequate warning to as what constitutes noncompliance for which penalties may be assessed.

Among the myriad applications of the due process clause is the fundamental principle that statutes and regulations which purport to govern conduct must give an adequate warning of what they command or forbid.... Even a regulation which governs purely economic or commercial activities, if its violation can engender penalties, must be so framed as to provide a constitutionally adequate warning to those whose activities are governed.

Diebold, Inc. v. Marshall, 585 F.2d 1327, 1335-36 (D.C. Cir. 1978). See also, Rollins Environemntal Services (NJ) Inc. v. U.S. Environmental Protection Agency, 937 F. 2d 649 (D.C. Cir. 1991).

While neither the are rules, This principle has been applied to hold that agency 'clarification', such as the <u>Statement of Interpretation</u>, the "Reporting Guide" nor the April 1992 amendments will not applied retroactively.

...a federal court will not retroactively apply an unforeseeable interpretation of an administrative regulation to the detriment of a regulated party on the theory that the post hoc interpretation asserted by the Agency is generally consistent with the policies underlying the Agency's regulatory program, when the semantic meaning of the regulations, as previously drafted and construed by the appropriate agency, does not support the interpretation which that agency urges upon the court.

Standard Oil Co. v. Federal Energy Administration, 453 F. Supp. 203, 240 (N.D. Ohio 1978), aff'd sub nom. Standard Oil Co. v. Department of Energy, 596 F.2d 1029 (Em. App. 1978):

The 1978 Statement of Interpretation does not provide adequate notice of, and indeed conflicts with, the Agency's current position at §8(e) requires reporting of all 'positive' toxicological findings without regard to an assessment of their relevance to human health. In accordance with the statute, EPA's 1978 Statement of Interpretation requires the regulated community to use scientific judgment to evaluate the significance of toxicological findings and to determining whether they reasonably support a conclusion of a substantial risk. Part V of the Statement of Interpretation urges persons to consider "the fact or probability" of an effect's occurrence. Similarly, the 1978 Statement of Interpretation stresses that an animal study is reportable only when "it contains reliable evidence ascribing the effect to the chemical." 43 Fed Reg. at 11112. Moreover, EPA's Statement of Interpretation defines the substantiality of risk as a function of both the seriousness of the effect and the probability of its occurrence. 43 Fed Reg 11110 (1978). Earlier Agency interpretation also emphasized the "substantial" nature of a §8(e) determination. See 42 Fed Reg 45362, 45363

(1977). [Section 8(e) findings require "extraordinary exposure to a chemical substance...which critically imperil human health or the environment"].

The recently issued "Reporting Guide" and April 1992 Amendment guidance requires reporting beyond and inconsistent with that required by the <u>Statement of Interpretation</u>. Given the statute and the <u>Statement of Interpretation</u>'s explicit focus on substantial human or environmental risk, whether a substance poses a "substantial risk" of injury requires the application of scientific judgment to the available data on a case-by-case basis.

If an overall weight-of-evidence analysis indicates that this classification is unwarranted, reporting should be unnecessary under §8(e) because the available data will not "reasonably support the conclusion" that the chemical presents a <u>substantial</u> risk of serious adverse consequences to human health.

Neither the legislative history of §8(e) nor the plain meaning of the statute support EPA's recent lowering of the reporting threshold that TSCA §8(e) was intended to be a sweeping information gathering mechanism. In introducing the new version of the toxic substances legislation, Representative Eckhart included for the record discussion of the specific changes from the version of H. R. 10318 reported by the Consumer Protection and Finance Subcommittee in December 1975. One of these changes was to modify the standard for reporting under §8(e). The standard in the House version was changed from "causes or contributes to an unreasonable risk" to "causes or significantly contributes to a substantial risk". This particular change was one of several made in TSCA §8 to avoid placing an undue burden on the regulated community. The final changes to focus the scope of Section 8(e) were made in the version reported by the Conference Committee.

The word "substantial" means "considerable in importance, value, degree, amount or extent". Therefore, as generally understood, a "substantial risk" is one which will affect a considerable number of people or portion of the environment, will cause serious injury and is based on reasonably sound scientific analysis or data. Support for the interpretation can be found in a similar provision in the Consumer Product Safety Act. Section 15 of the CPSA defines a "substantial product hazard" to be:

"a product defect which because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise, creates a substantial risk of injury to the public." Similarly, EPA has interpreted the word 'substantial' as a quantitative measurement. Thus, a 'substantial risk' is a risk that can be quantified, See, 56 Fed Reg 32292, 32297 (7/15/91). Finally, since information pertinent to the exposure of humans or the environment to chemical substances or mixtures may be obtained by EPA through Sections 8(a) and 8(d) regardless of the degree of potential risk, §8(e) has specialized function. Consequently, information subject to §8(e) reporting should be of a type which would lead a reasonable man to conclude that some type action was required immediately to prevent injury to health or the environment.

Attachment

Comparison:

Reporting triggers found in the 1978 "Statement of Interpretation/ Enforcement Policy", 43 Fed Reg 11110 (3/16/78) and the June 1991 Section 8(e) Guide.

TEST TYPE	1978 POLICY CRITERIA EXIST?	New 1991 GUIDE CRITERIA EXIST?
ACUTE LETHALITY		
Oral Dermal Inhalation (Vapors) aerosol dusts/ particles	N} N} N} N}	Y} Y} Y} Y}
SKIN IRRITATION	N	Y ⁸
SKIN SENSITIZATION (ANIMA	ALS) N	Y ⁹
EYE IRRITATION	N	Y ¹⁰
SUBCHRONIC (ORAL/DERMAL/INHALATION) N	Y ¹¹
REPRODUCTION STUDY	N	Y ¹²
DEVELOPMENTAL TOX	Y ¹³	Y ¹⁴

⁶43 <u>Fed Reg</u> at 11114, comment 14:

[&]quot;This policy statements directs the reporiting of specifiec effects when unknown to the Administrator. Many routine tests are based on a knowledge of toxicity associated with a chemicalL unknown effects occurring during such a range test may have to be reported if they are those of concern tot he Agency and if the information meets the criteria set forth in Parts V and VII."

⁷Guide at pp.22, 29-31.

⁸Guide at pp-34-36.

⁹Guide at pp-34-36.

¹⁰Guide at pp-34-36.

¹¹ Guide at pp-22; 36-37.

¹²Guide at pp-22

¹³⁴³ Fed Reg at 11112

[&]quot;Birth Defects" listed.

¹⁴Guide at pp-22

NEUROTOXICITY	N	Y ¹⁵
CARCINOGENICITY	Y ¹⁶	Y ¹⁷
MUTAGENICITY		
In Vitro In Vivo	Y} ¹⁸ Y}	Y} ¹⁵ Y}
ENVIRONMENTAL		
Bioaccumulation Bioconcentration Oct/water Part. Coeff.	Y} Y} ²⁰ Y}	N N N
Acute Fish	N	N
Acute Daphnia	N	N
Subchronic Fish	N	N
Subchronic Daphnia	N	N
Chronic Fish	N	N
AVIAN		
Acute	N	N
Reproductive	N	N
Reprodcutive	N	N

^{15 &}lt;u>Guide</u> at pp-23; 33-34. 1643 <u>Fed Reg</u> at 11112 "Cancer" listed

¹⁷ Guide at pp-21.
1843 Fed Reg at 11112; 11115 at Comment 15

"Mutagenicity" listed/ in vivo vs invitro discussed; discussion of "Ames test".

¹⁹Guide at pp-23. ²⁰43 Fed Reg at 11112; 11115 at Comment 16.

CAS # 3524-68-3

Chem: Pentaerythritol triacrylate
Title: Inhalation toxicity - acute and subacute

Date: 9/9/74

Summary of Effects: extremely toxic

Copies to: H. B. Hicks, Jr. (1) D. W. Woodward (1)

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E. I. du Pont de Nemours and Company Haskell Laboratory for Toxicology and Industrial Medicine

HASKELL LABORATORY REPORT NO. 593-74 NR

MR NO. 1791-001

Submitted by H. B. Hicks, Jr., Photo Products Department Parlir, New Jersey Other Codes SR-295 Haskell No. Pentaerythritol triacrylate (PETA) Material Tested

INHAIATION TOXICITY - ACUTE AND SUBACUTE

A. Acute Exposures

Houseline air passed through the tube and carried the resulting vapors into a 20-liter exposure Procedure: A syringe infusion rump metered the test material into a stainless steel tube maintained at 300°F Dilution air was added to the chamber containing six ChR-CD male rats of 250-286 grams initial body weight. stream just prior to the chamber inlet when necessary. in a furnace.

taken during each exposure. Nominal concentrations are based on the amount of material used per liter of air. Samples of the chamber atmosphere were taken periodically by scrubbing through 15.0 ml trichlorosolid-injection, gas chromatography (reported as 'analytical concentration'). At least three samples were ethylene contained in two impingers in series. The sam, les were sent to H. B. Hicks, Jr. for analysis by

Each exposure lasted four hours. Gross and histopathologic examinations were performed on two rats Survivors were weighed and observed daily for 14-days at each of seven and fourteen days post-exposure(1) after exposure unless sacrificed earlier,

77.6

⁽¹⁾ Microscopic examination performed by Dr. T. Chiu, Research Pathologist. Pathology Report No. 51-74.

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Results:

Observations	osure Post-Exposure	nia, 2/6 Foun	om 1 hour:15 1/6 Found dead - 3 hours nutes (3/6) 2/0 Found dead - 18 hours		7 Days:2/6 sacrificed 14 Days:2/6 sacrificed	ration, hypercmia 1 Day:mild weight loss (4/6) 2-14 Days:normal weight gain
	During Exposure	Inactive, gasping, salivation, hyperemia, face-pawing, pallor, death from 1 hour: 35 minutes (4/6)	Same as above; death from 1 hour:15 minutes - 3 hours:50 minutes (3/6)	Inactive, labored and irregular respiration, do that 3 hours:45 minutes (1/6)		Inactive, shallow respiration, hyperemia
Mortality	Ratio	9/9	9/9	2/6		9/0
Average Concentration in mg/liter	Analytical	(7.0844-0.2467)	C. 1028 (0.0733-0.1378)	*	,	0.0081
Average Conce	Nominal	1.62	0.62	0.43	ò	90.0

 $0.0081 \text{ mg/liter} < ALC^+ < 0.1028 \text{ mg/liter}$

Pathology (1): Under the test conditions outlined above, the test material appeared to have no adverse effects. The lesions revealed in the tissues (2) from test animals are commonly observed in rat colonies and are the result of intercurrent disease.

B. Subacute Exposure

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group of six ChR-CD male rats with average initial body weight of 249 grams was exposed to vapors of the heated (300°F) test material. A control group (same strain, birth date and body weight) was exposed to houseline air. Both groups were exposed to their respective atmospheres four hours/day for ten days. Three rats from each Procedure: Atmospheric generation and analytical procedure was the same as stated for the acute study. A group (test and control) were sacrificed after the last exposure and the remaining animals were sacrificed after a 14-day recovery period for gross and histopathologic examinations. Samples of the chamber atmosphere were taken twice during each exposure and analyzed as stated above.

Data not available.

Approximate Lethal Concentration,

The following tissues were examined microscepically: lung, trachea, liver, kidney and testis.

Results:

Average Nominal Concentration

Observations

During Exposure

C.099 mg/liter

Test Group Inactive, mild hyperemia, shallow respiration

None. Normal weight gain rate.

Post-Exposure

Average Analytical Concentration

Centrol Group

No material detected in any of samples submitted

None

None. Normal weight gain rate.

Pathology(3): No gross or microscopic alterations attributable to inhalation of the test material were observed in any of the test rats under conditions of this study. The lung, liver and kidney were examined microscopically (3)

(Analytical data for the minimum lethal exposure was not obtained because of an unidentified, interfering peak.) This range is considered extremely toxic based on four-hour inhalation exposures of rats. Histopathological changes observed in animals exposed to 0.43 mg/liter (nominal) were considered the result of intercurrent Summary: The Approximate Lethal Concentration (ALC) of PETA is between 0.0081 mg/liter and 0.1028 mg/liter. discase and not compound-related. Repeated exposure of a group of rats at 0.099 mg/liter (nominal) for ten days did not cause any cumulative toxic effects. However, analysis of the atmosphere from these exposures shoved no detectable amount of monomer.

from its reaction/hydrolysis products likely to be formed. The possibility of immune mechanisms needs investigation, advisable. However, an improved analytical method needs to be developed which can distinguish free acrylates test chambers and inability to assign a specific cause for the animal deaths, further experimental work is Because of the differences between nominal and analytical concentrations observed in the

PETA is as toxic as trimethylolpropane triacrylate(TAPTA) which has a four-hour ALC of 0.0401 mg/liter (4)

THE SHALL

Microscopic examination performed by R. N. Sharma, D.V.M. Pathology Report No. 76-74.

Haskell Laboratory Report No. 155-73.

Report by:

Choir M. Brown

Inhalation Toxicology Section

RMB: dhg

Date Issued: September 9, 1974 Report No. 593-74

N.B. E-3292, pp. 41-46 and 53-56.

Approved by:

Charles F. Reinhardt Associate Director

C/24.16. 1. /24.11



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

Mark H. Christman
Counsel
E. I. Du Pont De Nemours and Company
Legal D-7010-1
1007 Market Street
Wilmington, Delaware 19898

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

APR 1 8 1995

PA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) as emclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 1110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan

Risk Analysis Branch

Enclosure

12174A



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8(E) - 12174A

M/L

ACUTE INHALATION TOXICITY IN CD RATS IS OF MEDIUM CONCERN BASED ON AN LC50 BETWEEN 0.43 MG/L AND 0.62 MG/L. DOSAGES (NOMINAL, 4-HOURS) AND MORTALITY DATA ARE AS FOLLOWS: 0.06 MG/L (0/6); 0.43 MG/L (2/6); 0.62 MG/L (6/6); AND 1.62 MG/L (6/6). AT 0.06 MG/L AND ABOVE, TOXIC SIGNS INCLUDED INACTIVITY, FACE PAWING, GASPING, SALIVATION, AND HYPEREMIA.

SUBACUTE INHALATION TOXICITY IN MALE CD RATS IS OF LOW CONCERN. DOSAGES (NOMINAL, 4-HOURS/DAY FOR 10-DAYS) AND MORTALITY DATA ARE AS FOLLOWS: 0.099 MG/L (0/6). TOXIC SIGNS INCLUDED INACTIVITY, MILD HYPEREMIA AND SHALLOW RESPIRATION. GROSS AND MICROSCOPIC EXAMINATION REVEALED NO CHANGES ATTRIBUTABLE TO TEST SUBSTANCE.